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PAT. & T. M. OFFICE  
BOARD OF APPEALS

Appeal No. 588-11

DFB

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF APPEALS

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Ex parte Robert L. Lundak

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Application for Patent filed March 26, 1981, Serial No.  
247,656. High Fusion Frequency Fusible Lymphoblastoid Cell Line.

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Bertram I. Rowland et al. for appellant.

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Primary Examiner - Thomas G. Wiseman  
Examiner - John E. Tarcza

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Before Mattern, Serota, Sturtevant, Henon, Milestone, Merker,  
Blech, Katz, Goldstein, Pellman, Seidleck, Lovell, Bjorge,  
McKelvey, Winters, Steiner, Goolkasian and Rzucidlo,  
Examiners-in-Chief.

Pellman, Examiner-in-Chief.

This is an appeal from the examiner's decision finally  
rejecting claims 1 and 2, the only claims in the application.

The subject matter on appeal involves a novel human cell line which may be fused with lymphoid cells to produce hybridomas capable of secreting human monoclonal antibodies. To identify the claimed subject matter with greater particularity, claims 1 and 2 are reproduced as follows:

1. An immortal B-cell line WI-L2-729HF<sub>2</sub>.
2. A hybridoma resulting from the fusion of an immunized lymphocyte and a cell line according to Claim 1.

No references are cited by either the examiner or appellant.

The claims stand rejected for failing to comply with the requirements of 35 USC 112, first paragraph, because they are said to be based upon a disclosure that is inadequate to enable a person of ordinary skill in the subject art to make and use the claimed invention. At page 2 of the answer, the examiner explains that the basis for his rejection is appellant's failure to have had the claimed cell line deposited at an independent depository on or before the March 26, 1981 filing date of the application. The record shows that the claimed cell line was deposited at the American Type Culture Collection (ATCC) on April 2, 1981 and assigned Accession Number CRL 8062.

At page 2 of his brief, appellant states that the question before us is "whether the application filed on behalf of Professor Lundak was enabling at the time of filing as required by Title 35 USC §112 ¶1. If not, whether the application should be accorded a subsequent date." Beginning at page 4 of the brief, appellant denies that there is any requirement for a deposit of an organism at the time of filing an application. On the other hand, appellant states, if an organism must be deposited at the

time of filing, then a filing date should be accorded appellant as of the last act providing for a complete application. In support of his arguments, appellant relies upon the decisions in In re Argoudelis, 58 CCPA 769, 434 F.2d 1390, 168 USPQ 99 (1970) and Feldman v. Aunstrup, 517 F.2d 1351, 186 USPQ 108 (CCPA 1975).

Although careful consideration has been given to all of appellant's arguments and supporting authorities, we are unpersuaded of any reversible error in the examiner's rejection which will be sustained for essentially the same reasons set forth in the answer.

Appellant appreciates that the question of the filing date is not an appealable matter, but is petitionable. This is evidenced by the petition under 37 CFR 1.181 filed by appellant on May 6, 1983. Consequently, since this matter is not within our jurisdiction, we decline to make any decision or comment relating thereto.

We acknowledge that the cell line at issue is not a "naturally occurring organism," but a cell line that has been subjected to certain procedures to enhance its fusion frequency a thousand fold. The chances that a person of ordinary skill in the art could obtain the same results without undue experimentation were considered by the examiner to be so remote that he found claims 1 and 2 free from the prior art. Accordingly, since the examiner has treated the modified cell line in the same manner as a new microorganism and since no countervailing reasons have been provided by appellant to employ a different procedure, we shall follow the examiner's practice in this case. Thus, for purposes of this appeal, the claimed cell line is considered in the same light as a new microorganism.

At page 5 of his brief, appellant states that there is no statutory basis for requiring a deposit of a microorganism. We disagree. Clearly, 35 USC 112 requires a written description of the invention such that a person skilled in the art will be enabled to make and use the same. However, where new microorganisms are essential to the invention, the mere description of the microorganism is inadequate to enable said person "to make and use" the invention. Therefore, in the absence of some additional procedure whereby the description in the specification might be supplemented, inventions involving a previously unknown unique microorganism would not comply with the statutory requirements of 35 USC 112. Nevertheless, to afford the opportunity of obtaining patent protection to inventors in the field of microbiology, the PTO, following applicable case law, has for many years construed the deposit of a culture of a new microorganism, in a suitable depository, no later than the effective U.S. filing date of the application, as acceptable compliance with the enablement portion of the statute. Compare MPEP 608.01(p)C.

Since it is not desirable to have an applicant submit a culture with the application for patent (the PTO does not have the storage facilities or the expertise to maintain such cultures), a variation in the usual requirements of 112 was developed. An applicant is still required to file the written description with the PTO; however, in addition, a viable sample of the new culture must be deposited with a recognized depository. Together, the written description and the deposited culture define the invention so that one skilled in this art is enabled to make and use the invention. Without the deposit, there would be no enablement.

The written specification by itself would be insufficient to receive a filing date under Section 111\*.

Consequently, the requirement for the deposit of the microorganism no later than the filing date of the application does not discriminate against an applicant, as urged at page 11 of appellant's brief. Rather, each member of this class of applicants is provided with a method of protecting his or her invention involving a microorganism, although such invention would otherwise be incapable of being disclosed by a written description as required by Section 112. The PTO's interpretation of the statute is for the microbiologist's express benefit.

Appellant's claimed cell line is unique and it does not appear to be reasonably possible to duplicate the cells even by treating them according to the procedure described in the specification. Cells are not like chemical compounds and cannot be modified in the same way, even when the treating technique is kept uniform. Accordingly, since appellant's cell line is unique in the same sense as a new microorganism, the same PTO-recognized system is suitable and should be followed, i.e. deposit of the cell line in a recognized depository.

The question of adequate disclosure of new microorganisms has been recently addressed with respect to multinationally filed patent applications. The Budapest Treaty and the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure came into force on August 19, 1980 with the United States as a signatory. See 961 O.G. 21-26, published August 23,

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\*35 USC 111. Application for patent

"An application shall include (1) a specification as prescribed by section 112 of this title;..."

1977. In a Memorandum by Commissioner Diamond published at 999 O.G. 2 on October 7, 1980, regarding the objectives of the Treaty, the following explanation is offered (paragraph 2):

"Disclosure of the invention is a generally recognized requirement for the grant of patents (for the purposes of this memorandum, the word 'patent' also covers other titles of protection, such as inventors' certificates). Normally, an invention is disclosed by means of a written description. Where an invention involves the use of a microorganism that is not available to the public, such a description is not sufficient for disclosure, since the invention could not be used by a person skilled in the art. That is why in the patent procedure of an increasing number of countries it is necessary not only to file a written description but also to deposit, with a depository institution, a sample of the microorganism."

The treaty is not cited to "modify the clear and unambiguous language of Title 35," as suggested by appellant at page 8 of his brief. Instead, we provide the noted quotation to further demonstrate that appellant's written description, without a proper deposit, failed to comply with the requirements of 35 USC 112 at the time of filing.

Also, the prerequisites for an institution to be recognized as a proper depository are enumerated at paragraph 5 of Commissioner Diamond's Memorandum.\* They answer appellant's argument that it was

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\* "Requirements Which Have to be Met by International Depository Authorities

5. The requirements referred to in paragraph 3 above which a depository institution has to meet in order to become a depository authority are the following (Article 6(2) and Rule 2):

(a) The institution has to have a continuous existence. It has to be impartial and objective-which means among other things that it has to be free of any dependence on interests that are liable to prejudice the disinterested performance of its functions-and it has to be available, for the deposit of microorganisms, to any (Footnote continued on next page)

sufficient to comply with 112 that "the subject cell line was maintained at three separate locations by members of the faculty of the University of California" (the apparent assignee of the present invention). Appellant has not established that the faculty members at those three locations met, or indeed could meet, the minimum qualifications reasonably necessary for recognition as a PTO-permitted depository. Nor can it be said that they, individually or collectively, met or could meet the basic requirements instituted by international agreement.

In appellant's discussion of the decision in Feldman v. Aunstrup, supra at pages 8-9 of the brief and at page 4 of the reply brief, appellant quotes from the court's decision and emphasizes that, according to the court, enablement does not require assured public access to a microorganism deposit as of the filing date. A

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(Footnote continued from previous page) depositor under the same conditions. These requirements, which in fact seem self-evident, are designed to give the public in general and depositors in particular fundamental guarantees of reliability as to the smooth operation of the system. On the other hand, the legal status of the institution is irrelevant: it may be either public or private.

(b) The institution has to have the necessary staff and facilities to perform its scientific and administrative tasks, which consist among other things in:

(i) accepting for deposit any or certain kinds of microorganisms;

(ii) examining the viability of the microorganisms deposited with it and issuing a receipt to the depositor and any required viability statement (see paragraphs 7 and 8 below);

(iii) storing the deposited microorganism for at least 30 years (Rule 9(1)) in such a way as to keep them viable and uncontaminated;

(iv) providing for sufficient safety measures to minimize the risk of losing the deposited microorganisms;

(v) complying with respect to the microorganisms deposited under the Treaty with the requirement of secrecy which means giving no information to anyone on the question whether a microorganism has been thus deposited and giving no information to anyone (except to a person who is entitled to a sample-see paragraph 10 below) on any microorganism thus deposited (Rule 9(2));

(vi) furnishing, rapidly and in an appropriate manner, samples of the deposited microorganisms to all those who are entitled to such samples (see paragraph 10 below)."

clear distinction exists between making the deposit of a microorganism culture in order to comply with 35 USC 112, and assuring unrestricted public access to the culture. As with any U.S. patent application, the public should not generally have access until a patent issues. Thus, we do not consider that the court was offering any alternative to the deposit procedure that had been found acceptable by the Patent Office. The court was merely dealing with the question previously decided in the Argoudelis case, supra.

The reason for the Office's insistence on a deposit no later than the application filing date is believed to be self-evident. An invention must be completely disclosed in an application, as filed. Any subsequent addition of disclosure to the case is new matter and is proscribed by 35 USC 132. Where a new microorganism is concerned, its deposit likewise must be made no later than the application filing date or the application disclosure will be fatally defective. The subsequent deposit, like later additions to the disclosure of other applications, would constitute new matter.

In an analogous situation, the Court of Customs and Patent Appeals held in In re Glass, 492 F.2d 1228, 1232, 181 USPQ 31, 34 (CCPA 1974), that "[t]he sufficiency [of a disclosure of a patent application] must be judged as of the filing date [of the patent application]." Glass resolved an issue which the CCPA did not need to decide in In re Argoudelis, supra, and which the CCPA expressly reserved in In re Barrett, 440 F.2d 1391, 1393 n. 2, 169 USPQ 560, 561 N. 2 (CCPA 1971). The decision in Glass is binding precedent. South Corp. v. United States, 690 F.2d 1368, 215 USPQ 657 (Fed. Cir. 1982). Glass is entirely consistent with an earlier decision in Turchan v. Bailey Meter Co., 167 F. Supp. 58, 64, 119 USPQ 165, 169 (D. Del. 1958). The holding in Glass is also consistent with a long-standing practice, both in the federal courts and the Patent



and Trademark Office, of according to an inventor a constructive reduction to practice as of the date the inventor files a patent application which contains an enabling disclosure. 1 Rivise and Caesar, Interference Law and Practice, 154, 155, 158, and 159 (Michie Co. 1940); Reese v. Hurst v. Wiewiorowski, 661 F.2d 1222, 1237 n. 12, 211 USPQ 936, 950 n. 12 (CCPA 1981); Automatic Weighing Machine Co. v. Pneumatic Scale Corp., 166 F. 288, 297, 1909 C.D. 498, 507 (1st Cir. 1909); Boyce v. Anderson, 451 F.2d 818, 820, 171 USPQ 792, 793 (9th Cir. 1971). The CCPA's decision in Glass, by itself, should be dispositive of this appeal.

As of March 26, 1981, the filing date, appellant's patent application did not contain a disclosure which would have enabled a person skilled in the art to make and use the invention sought to be patented. Nor has appellant shown, on this record, that the "cell line" which is essential to make and use the invention, was generally known or available through any reasonable source, including an appropriate depository. The timely deposit of a new cell line provides a simple and orderly procedure that is clearly defined for the applicant and is reasonably administrable for this Office. Since the procedure long followed by the Patent and Trademark Office to fulfill the enablement provision of 112 is not contrary to any statute or court decision, and since it has not been shown to be unreasonable or unfair, compliance therewith is properly required. Appellant's failure to comply in this application requires us to sustain the examiner's rejection.

While not necessary to our decision, we are constrained to point out that appellant's culture deposit conditions in 1981 fail, in yet another important respect, to comply with both the PTO-established procedure and the provisions of the 1980 Budapest Treaty (to which, we repeat, the United States was a signatory).

Specifically, the conditions under which appellant deposited the novel cell line in the American Type Culture Collection are inadequate from a storage duration viewpoint.

Appellant's deposit was made under contractual arrangement such that the deposit would be maintained for patent purposes for a period of 20 years after the date of deposit. At the end of the 20 years, the disposition of the deposit is at the discretion of the ATCC which is then free to discard it. Appellant's deposit was made in April, 1981. Maintenance by the ATCC for patent purposes expires in April 2001, several months before the earliest possible expiration date of any patent which could issue on this application. Should the ATCC decide to discard the deposited cell line in April 2001, the public will be unable to make or use the claimed invention without obtaining the cell line from appellant or his then-assignee. This frustrates the basic intent of Congress (35 USC 112) to ensure that the public can practice the invention.

Indeed, by not contracting for culture maintenance and public availability after expiration of a patent, we believe that appellant has frustrated that important feature of our patent laws which ensures that the public may freely practice the invention claimed in an expired patent. The permanent availability of a deposited microorganism essential for making and/or using the subject matter claimed in a patent is a legitimate ground for concern on the part of the Patent and Trademark Office. See the Argoudelis case, supra, where the deposit had been made under conditions such that the recognized public depository was "under a contractual obligation to place the culture in the permanent collection". 58 CCPA 775, 434 F.2d 1394, 168 USPQ 103.

We are well aware that the maintenance of a living organism on deposit is not as simple as the storing of a paper or microfilm document. The organisms are most often freeze dried and

stored in refrigerators, or kept under frozen conditions at the temperature of liquid nitrogen. Often, even when afforded the greatest care, they die, mutate or otherwise become worthless. Under such conditions "permanence," which is generally synonymous with "forever," becomes a very long and expensive condition which may yield little or no benefit to the public when the culture maintained is of no commercial or scientific interest.

The Court of Customs and Patent Appeals has previously considered the possibility that an initially "enabling" disclosure might become "unenabling." See In re Metcalfe, 56 CCPA 1191, 410 F. 2d 1378, 161 USPQ 789 (1969). In Metcalfe, the applicant had identified certain resins used to make the invention claimed by reference to their trademark and tradename. The Court recognized that the manufacturer of the trademarked resins could discontinue the manufacture thereof at any time but adopted a rule of reason approach stating (161 USPQ 789 at 792),

"...it is always possible that the practice of a given patented invention may become impossible because an essential material (or even apparatus) becomes unavailable due to a lack of raw materials, public disaster, or other occurrence not within the control of the patentee; and this possibility exists whether or not the 'essential material' was identified in the patent only by trademark. What we are driving at is this: (1) there is always the possibility that sometime after the issuance of a patent, the disclosure which was initially enabling may become 'unenabling' and (2) whether a given disclosure which identifies a material to be employed in the practice of the claimed invention is 'enabling' within the meaning of 35 USC 112, must be decided by a rule of reason applied to the facts of the case."

We suggest that a similar "rule of reason" approach has generally inhered, and should continue to inhere, in the culture deposit procedure, by insisting that the depository be contractually obligated

to maintain the deposit for at least a reasonable time after expiration of the patent rights.

Reverting to the Budapest Treaty, we point out that Rule 9.1 thereof provides:

"Any microorganism deposited with an international depository authority shall be stored by such authority, with all the care necessary to keep it viable and uncontaminated, for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism was received by the said authority and, in any case, for a period of at least 30 years after the date of the deposit."


Such conditions are minimum international requirements and appear to be manifestly within the rule of reason for U.S. applications espoused by Metcalf. The 30-year or more storage duration should almost invariably ensure public availability after expiration of the 17-year term of a U.S. patent, and indeed maintenance of the culture for as long as the public expresses the slightest interest in it.

For the reasons explained in the answer and those discussed above, the examiner's decision rejecting claims 1 and 2 is affirmed.

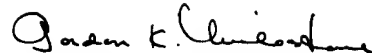
AFFIRMED


Fred C. Mattern, Jr.  
Fred C. Mattern, Jr.  
Examiner-in-Chief


Brereton  
Sturtevant  
Brereton Sturtevant  
Examiner-in-Chief

  
Paul J. Henon, Jr.  
Examiner-in-Chief


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Examiner-in-Chief

  
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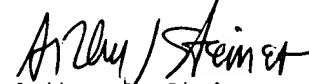
  
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McKelvey, Examiner-in-Chief, with whom Serota, Examiner-in-Chief, joins, concurring.

The primary examiner properly refused to allow claims 1 and 2 of the application on appeal. Our reasons for reaching this conclusion differ from those stated in the majority opinion.

In Feldman v. Aunstrup, 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), cert. denied, 424 U.S. 912 (1976), the CCPA noted, 517 F.2d at 1355, 186 USPQ at 112:

" . . . the enablement requirement of 112, first paragraph, does not require [public] . . . access to a microorganism deposit as of the filing date; what is required is assurance of access [by the PTO] . . . prior to or during the pendency of the application . . . " (emphasis by the CCPA).

Based on Feldman, it would appear that there are only two conditions with which an applicant must comply in so-called "microorganism" type cases in order to insure that his or her disclosure is enabling as of the filing date. First, the PTO must be assured of access to the "microorganism" during pendency of the application. This requirement is bottomed on 35 USC 114 and 37 CFR 1.93 which authorize the PTO to require samples. Presumably if an applicant fails to provide a requested sample, his or her application would be held abandoned. 35 USC 133. Second, the public must be entitled to access to the "microorganism" after the patent issues so that "the public will, in fact, receive something in return for the patent grant." In re Argoudelis, 434 F.2d 1390, 1394, 168 USPQ 99, 103 (CCPA 1970) (Baldwin, Jr., concurring).

The majority opinion does not cogently come to grips with Feldman. It is true that a disclosure must be enabling as of the filing date of an application. In re Glass, 492 F.2d 1228, 181 USPQ 31 (CCPA 1974). In "microorganism" type cases the CCPA has held that if the first of the two above-discussed conditions are met, the disclosure is enabling as of the filing date. There is no inconsistency between the holdings of Feldman and Glass; the only difference is the evidence required to prove enablement and that evidence will depend on the kind of case being considered.

Turning to the evidence in this case, an applicant has the burden of proving that he or she has complied with the two above-discussed conditions. After all, the PTO does not know what "microorganism" a particular applicant may have or what that

applicant may have done with the "microorganism" to preserve it and/or make it available to the public.

The application on appeal was filed on March 26, 1981. According to his declaration, applicant Robert Lundak states:

"On March 26, 1981 . . . and at all times thereafter, the W1-L2-729-HF<sub>2</sub> hybridoma cell line [which is claimed in the application on appeal] was stored at the University of California, Riverside, at three separate locations, including my own laboratory, the laboratory of Dr. Bruce Devens, and the laboratory of Dr. Richard Lubin.

\* \* \* \* \*

"The cell line was also stored at the laboratory of Dr. John Lewis at the Loma Linda University Medical Center, Loma Linda, California.

\* \* \* \* \*

"At all times since March 26, 1981 . . . the subject W1-L2-729-HF<sub>2</sub> cell has been maintained by me, and by others on my behalf, with all necessary precautions taken to assure its permanence and availability."

Appellant's statements concerning storage by Dr. Devens, Dr. Lubin and Dr. Lewis are inadmissible hearsay insofar as the statements are offered to prove the truth of the matter asserted. Compare Rule 801(c) of the Federal Rules of Evidence. Appellant's statement, however, proves by a preponderance of evidence (i.e., something is more likely true than not) that he was in possession of the cell line on March 26, 1981 and that he maintained the cell line between March 26, 1981 and at least the date he signed his declaration, viz., March 23, 1983. Hence, the cell line was available between March 26, 1981, and March 23, 1983, to the PTO had the PTO asked for a sample. Accordingly, appellant has met the first of the two conditions at least for the period of pendency between March 26, 1981, and March 23, 1983.

In order to show that the cell line would have been available throughout the period of the prosecution of this application, appellant contends that it was deposited with the American Type Culture Collection (ATCC). Unfortunately for appellant, the evidence presently in the record will not support the finding which he wants the PTO to make.

Appellant's evidence is not sufficient to prove that the cell line in his possession on March 26, 1981 is the cell line which was deposited in the ATCC. Since the record will not support a finding that the cell line in appellant's possession on March 26, 1981, is the same as the cell line deposited with the ATCC on April 2, 1981, appellant has not sustained his burden of proving that the cell line will be permanently available to the public when any patent is issued. Feldman v. Aunstrup, 517 F.2d at 1356, 186 USPQ at 113.

Inasmuch as the rationale upon which this opinion is based is "new," we would affirm the examiner's rejection while at the same time making the affirmance a new ground of rejection under 37 CFR 1.196(b). By making a 1.196(b) rejection, appellant would have an opportunity to supplement the record, if he can, to prove a chain of custody between himself and the ATCC.


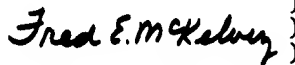
The legal issue raised in this appeal is a significant issue. Judicial resolution of the issue no doubt would be helpful to both inventors and the PTO. However, on the present record, a reviewing court would be hard-pressed to reach the legal issue inasmuch as the evidence "of record" would support an affirmance on a narrow factual basis regardless of the position any court might take on the law. Should appellant decide to seek judicial review, it is our hope that he would (1) file a continuation and



supplement the record with chain of custody evidence or (2) petition the Commissioner for leave to reopen prosecution of this application to supplement the record.

Appellant maintains that the cell line was deposited with the ATCC on April 2, 1981. To be sure, there is a copy of a letter in the record purportedly signed by Mrs. Bobbie A. Brandon, Head of Professional Services Department of ATCC in which it is stated that a cell line with a "Depositor's Reference" W1-L2-729-HF<sub>2</sub> was deposited with the ATCC on April 2, 1981. The letter is not in declaration form and therefore is not admissible. 37 CFR 1.132. Even if the letter were admissible, all it would prove is that the ATCC received a sample in a bottle which was labelled W1-L2-729-HF<sub>2</sub>. No employee of ATCC has stated in declaration form what was in the bottle. Receipt of a bottle by ATCC is not proof that appellant forwarded the cell line to ATCC.

The record also contains a letter dated April 8, 1981, signed by counsel for appellant and a declaration signed by counsel. The letter and declaration do not purport to state, based on first-hand knowledge, that the cell line was deposited with the ATCC on April 2, 1981. There are allegations in the various briefs that the cell line was deposited on April 2, 1981. However, the argument of counsel in a brief cannot take the place of evidence in the record. Meitzner v. Mindick, 549 F.2d 775, 193 USPQ 17 (CCPA 1977), cert. denied, 434 U.S. 854 (1977).

  
Saul I. Serota  
Examiner-in-Chief  
  
Fred E. McKelvey  
Examiner-in-Chief

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Rzucidlo, Examiner-in-Chief, Blech, Seidleck, Goolkasian,  
Examiners-in-Chief, concurring:

The decision of the examiner, in finally rejecting the claims on appeal, should be affirmed in that appellant has not provided evidence sufficient to overcome a prima facie case of nonenablement. We disagree with the conclusion reached by the majority that appellant's failure to have made a deposit of the instant cell line on or before the filing date of the instant application causes the specification to be "fatally defective".

A proper application of the law to the facts of the instant appeal initially requires an understanding of the dual role played by the "enablement" provisions found in 35 USC 112. In its first role, the enablement provision of §112 ensures that the disclosure accompanying the patent is such that one of ordinary skill in the art to which the patent pertains will be able to "make and use" the invention recited in the claims of the patent. This aspect of the enablement requirements of §112 requires only that the disclosure be adequate as of the issue date of the patent. See Argoudelis and Feldman cited, supra.

The second role of the enablement provisions of §112 is related to the fact that the filing date of a patent application is regarded as the prima facie date of invention (the so-called constructive reduction to practice). It is essential that at the time of filing of an application there be no question that the disclosure of the application evidences a completed invention. No technological problems the resolution of which require more than ordinary skill and reasonable time remain in order to obtain an embodiment of the claimed invention.

A detailed legal analysis of the dual considerations that must be afforded the enablement aspect of 35 USC 112 is set forth in the concurring opinion of Judge Baldwin in Argoudelis cited, supra.

From the record before us, it is clear that appellant has produced a new cell line and a hybridoma resulting from the fusion of an immunized lymphocyte and the instant cell line.

A cell line labelled as W<sub>1</sub>-L2-729 HF<sub>2</sub> (appellant's designation) was received by the American Type Culture Collection (hereinafter, ATCC) on April 2, 1981. The ATCC is a recognized depository. The April date is subsequent to the filing date of the instant application. It is evident from the instant record that the instant cell line will be available from the depository to anyone seeking a sample thereof after the issuance of a patent to appellant which contain claims covering the cell line and the hybridoma.\* This deposit by appellant causes the instant disclosure to come into compliance with the first role played by the enablement requirement noted hereinabove.

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\* It might be noted that appellant specified in his agreement with ATCC that the cell line be maintained for 20 years. This time period would expire prior to the expiration date of any patent which would issue to appellant based upon the instant application. We concur with the majority's conclusion that the 20 year storage duration is inadequate. A time period such as provided for in Rule 9.1 of the Budapest Treaty would most likely be within the rule of reason expressed in In re Metcalfe, 56 CCPA 1191, 410 F.2d 1378, 161 USPQ 789 (1969).

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The fact that the date of deposit in a recognized depository is later than the filing date of the instant application is of little relevance when compliance with the first aspect of the enabling provision of §112 is being determined. The skilled artisan seeking to reproduce the new cell line after issuance of a patent to the cell line would have the necessary access to the deposited cell line as long as a deposit of the cell line was made prior to the issuance of the patent. If a complete disclosure as to the requirements for growing the cells was presented in the patent specification, making and using the cells covered by the patent would be no problem for the artisan seeking to do so.

In the instant situation, the examiner has not criticized appellant's disclosure as to its completeness in setting forth the conditions under which the instant cell line can be cultured. It would appear that the examiner understood what is the scope and content of the subject matter of the instant invention and concluded that the written description was complete to the extent possible in cases involving a new cell line in setting forth the parameters necessary for one to be able to produce cells and hybridomas such as recited in the claims on appeal. The basis for the examiner's rejection is not directed to anything lacking in the written disclosure but rather to the fact that appellant's cell deposit was made on April 2, 1981, while the filing date of the instant application is March 26, 1981.

This delay in making the deposit would not cause appellant to be in derogation of the requirements of the first aspect of the §112 enablement provision of the statute because the deposit was made prior to the issuance of a patent based upon the instant application. Access to the cell line by the PTO is assured by 35 USC 114 during the pendency of the application before the Office.

The second aspect of the §112 enablement provision differs from the first aspect in that applicant must demonstrate that, as of the filing date of the application for patent, the claimed invention was complete, i.e., actually capable of being reduced to practice without unreasonable technological problems. Normally, the written description comprising an applicant's disclosure is sufficient for this requirement. However, in the case of microorganisms or cell cultures, a written description is inadequate and something more is needed to comply with this portion of the enablement requirement. The most desirable way to satisfy this requirement in the case of a new microorganism or cell culture is to make a deposit of the claimed material with a recognized depository. Appellant, in the instant case, has, because of apparent inadvertence, failed to make the deposit on or before the filing date of the instant application. A deposit was made several days after the filing date after appellant's attorney discovered the problem and informed appellant thereof.

The majority notes that the basis for the examiner's rejection was "appellant's failure to have had the claimed cell line deposited at an independent depository on or before the

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March 26, 1981 filing date of the application." The majority does not say that the cell line was not in existence or that the cell line was not available, through applicant, to the examiner or the Commissioner of Patents by means of 35 USC 114 or to the public by means of 35 USC 122. Rather the majority focuses on deposition in an independent depository prior to filing. There does not appear to be any statutory or case law basis for this supposition on the part of the majority.

The question before this panel is whether or not appellant's late deposit causes the instant application to be non-enabling as of the filing date of the application.

In the majority opinion, Glass has been cited as being dispositive of the issues in the instant appeal. Glass holds that "it is an applicant's obligation to supply an enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention." The Court in Glass found that the disclosure of the Glass application left "too much to conjecture, speculation and experimentation and is, therefore, insufficient in law to support any of the appealed claims."

In the instant application, what the examiner is really questioning is the existence of a pure cell culture as of the filing date of the application. The examiner, in effect, concludes that since a deposit in an independent depository was not made on or before the filing date, appellant cannot properly be said to have constructively reduced the invention to practice as of that date.

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The fact situation in the instant appeal differs from that in Glass. Appellant does not seek to present any new information which became available only after the filing of the instant application. Pages 10 and 11 of appellant's brief which are directed most specifically to the question before us indicate that appellant seeks to present evidence which was neither the work of others nor which refers to events which occurred after the filing date of the instant application. In this sense, the question before us is whether or not a deposit in an independent depository is the sole means by which evidence of enablement can be presented by an applicant.

We conclude that while a deposit may be the most desirable form in which such evidence can be presented, it is not the exclusive way in which an applicant may carry his burden in overcoming a prima facie case of non-enablement.

The Lundak and Rowland declarations submitted by appellant are, in our view, insufficient. Lundak asserts that as of the filing date of the instant application, he, as the inventor, had possession of the cell line recited in the claims on appeal. In addition, declarant states that, as of the filing date of the instant application and thereafter, the cell line was maintained at his own laboratory, two other laboratories at the University of California, Riverside and at a laboratory at the Loma Linda Medical Center. The cell line was stored at all locations under such conditions as to assure the permanent maintenance and availability of the cell line and to protect against accidental

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loss. The Rowland declaration relates to the circumstances surrounding the deposit of the instant cell line. As to the actual desposit, declarant simply states that Dr. Lundak, appellant herein, "investigated and found in fact the cell line had not been sent and promptly corrected the situation."

The evidence before us is lacking in several important aspects. Dr. Lundak, who is alleged to have "promptly corrected the situation" by declarant Rowland has made no averments in his declaration relative to the deposit which was sent to the independent depository. No chain of possession of the instant cell line between the filing date of this application and the receipt of the cell line at ATCC has been established. No declaration evidence has been submitted from some one at ATCC attesting to the actual receipt of the material sent by Dr. Lundak to ATCC. As to the maintenance of the instant cell line at locations other than appellant's laboratory, the instant record contains only the assertions of Dr. Lundak. Corroboratory declarations from someone at each of the other laboratories attesting to the presence of the cell line in the laboratory and the conditions under which it was maintained should be presented.

While we would affirm the examiner's rejection, our reasoning is quite different from that of the majority and the examiner and hence, we consider our affirmance to be a new rejection made under the provisions of 37 CFR 1.196(b). While appellant has not overcome the prima facie case of non-enablement made out by the examiner by the evidence of record he should now be afforded the opportunity to present new evidence.



It might further be noted that there is little legal distinction between the facts surrounding the deposit in this case and the facts surrounding the deposit in Feldman v. Aunstrup, supra. In Feldman, at the time of filing the U.S. application, the microorganism was maintained in a depository in which there was no guarantee or assurance of access to the microorganism by the public. Appellant's maintaining of the cell line in four separate locations is no less a deposit than that which existed in Feldman.

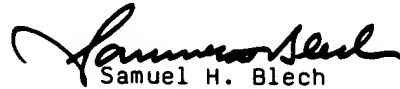
In Feldman, the court states where:

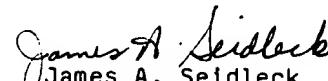
It is true, as Feldman asserts, that as of the 1966 filing date of Aunstrup's U. S. application, there was no guarantee or assurance of access to CBS 370.65 by the public upon issuance of a U. S. patent on the application. However, the enablement requirement of §112, first paragraph, does not require such assured access to a microorganism deposit as of the filing date; what is required is assurance of access (to the microorganism culture by the public upon issuance of a patent on the application) prior to or during the pendency of the application, so that, upon issuance of a U. S. patent on the application, "the public will in fact, receive something in return for the patent grant." In re Argoudelis, 58 CCPA at 776, 434 F.2d at 1394, 168 USPQ at 103 (Baldwin, J., concurring).

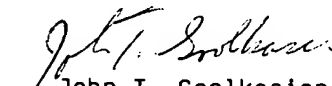
At the time Aunstrup's U. S. application was filed, the invention recited in the count and described in the application was fully capable of being reduced to practice (i.e., no technological problems, the resolution of which would require more than ordinary skill and reasonable time, remained in order to obtain an operative, useful process). Thus, the so-called "second aspect" or second function of §112, first paragraph -- that of establishing the application filing date as the prima facie date of invention -- was satisfied by Aunstrup's specification. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973).


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Appellant has satisfied both requirements of §112 in essentially the same manner as did Aunstrup of the Feldman decision.

  
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